

# **Notice of Allowability**

**Application No.**

09/872,968

**Examiner**

Deborah Crouch, Ph.D.

**Applicant(s)**

WANDS ET AL.

**Art Unit**

1632

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment filed December 22, 2003.
2. ☒ The allowed claim(s) is/are 21,23-25,50-54,56,58 and 59.
3. ☒ The drawings filed on 01 June 2001 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

## **Attachment(s)**

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

Deborah Crouch, Ph.D.  
Primary Examiner  
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An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Ms. Ingrid Beattie on March 9, 2004.

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims:

1 - 20. (Previously Canceled)

21. (Currently Amended) A non-transgenic model for Alzheimer's Disease, comprising a non-human mammal, wherein the neuronal cells of said mammal comprise a composition comprising a heterologous AD7c-NTP nucleic acid, histone, and amphipathic compound, and wherein expression of said heterologous AD7C-NTP nucleic acid is detected in neuronal tissue of said mammal at least 4 weeks after contacting said mammal with said composition and wherein said expression results in Alzheimer's Disease-associated neuronal cell death.

22. (Previously Canceled).

23. (Currently Amended) The model of claim 21, wherein said mammal is a rodent.

24. (Currently Amended) The model of claim 21, wherein said mammal is a non-human primate.

25. (Previously Presented) The model of claim 21, wherein said neuronal cell is selected from the group consisting of a cortical neuronal cell, a hippocampal neuronal cell, a cerebellar neuronal cell, and a glial cell.

26-49 (Previously Canceled).

50. (Previously Amended). A method of identifying a compound which inhibits Alzheimer's Disease-associated neuronal cell death, comprising contacting the model of claim 21 expressing a heterologous AD7c-NTP nucleic acid in a neuronal tissue of said animal with a candidate compound and measuring neuronal cell viability, wherein an increase in cell viability in the presence of the compound compared to in its absence indicates that said compound inhibits Alzheimer's Disease-associated neuronal cell death.

51. (Currently Amended). A method of identifying a compound which inhibits amyloid precursor protein (APP) expression comprising contacting the model of claim 21 with a candidate compound and detecting (APP) expression in neuronal tissue of said mammal, wherein a decrease in APP expression in the presence of the compound compared to in its absence indicates that said compound inhibits expression of APP.

52. (Currently Amended). A method of identifying a compound which inhibits amyloid plaque formation, comprising contacting the model of claim 21 with a candidate compound and detecting amyloid plaques

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in neuronal tissue, wherein a decrease in the amount of said plaques in the presence of the compound compared to in its absence indicates that said compound inhibits amyloid plaque formation.

53. (Currently Amended). The model of claim 21, wherein said AD7c-NTP nucleic acid comprises the nucleotide sequence of SEQ ID NO:1.

54. (Currently Amended). The model of claim 21, wherein said wherein expression of said heterologous AD7c-NTP nucleic acid is detected in neuronal tissue of said mammal at least 2 months after contacting said mammal with said composition.

55. (Canceled)

56. (Previously Presented). The method of claim 21, wherein said histone is selected from the group consisting of H1, H2A, H2B, H3, and H4.

57. (Canceled)

58. (Previously Presented). The method of claim 21, wherein the amphipathic compound is a non-natural polyamine having a hydrophobic moiety, said polyamine being selected from the group consisting of a C6-C24 alkane, C6-C24 alkane, sterol, steroid, lipid, fatty acid, and hydrophobic hormone.

59. (Previously Presented). The method of claim 21, wherein said nucleic acid is an AD7c-NTP antisense molecule or a nitric oxide synthase III antisense molecule.

2. The title has been changed to -- A Non-Transgenic Nonhuman Model for Alzheimer's Disease using a AD7c-NTP Nucleic Acid --.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Crouch, Ph.D. whose telephone number is 571-272-0727. The examiner can normally be reached on M-Th, 8:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0408. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Deborah Crouch, Ph.D.  
Primary Examiner  
Art Unit 1632

March 10, 2004